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CENTRAL FAX CENTERApplication Serial No. 10/588,171
Reply to office action of October 29, 2007

MAR 31 2008

PATENT
Docket: CU-4989**Amendments To The Specification**

Please replace paragraph [0019] in the specification, page 4, lines 7-15 with the following amended paragraph:

The present invention generally relates to an improvement to percutaneous lead assemblies. A first preferred embodiment of this invention is shown in FIG. 1. In this embodiment, a patient 1 is implanted with implanted medical device ~~a medical assist device~~ 2 to assist or enhance the patient's body function. Preferably, this medical assist device may be active or passive and may require uni- or bi-directional data, instructions, and/or power in the form of electrical signals from the external environment. Preferably, these electrical signals may be communicated by an external controller 7. Please note that it may be preferable to use this embodiment in conjunction with an implantable blood pump or a left ventricle assist device.

Please replace paragraph [0023] in the specification, page 5, lines 7-15 with the following amended paragraph:

[0023] The percutaneous lead assembly 10 has a first portion 8 and a second portion 4. The second portion 4 may extend from the first connector 3 through the aperture 5 and join with the first portion 8. Preferably, the section of the lead referred to as the second portion 4 may include regions coated with a textured surface. This textured surface may be produced by coating the region of the lead with velour or ~~Dacron-TM~~. DACRON® polyester. These types of coating materials promote ingrowth of the patient's cells into the surface of the textured surface and assist in anchoring lead assembly 10 within the patient's body 1. It is also preferred to only coating the lead portions, where necessary to achieve the desired amount of ingrowth or anchoring within the body 1.

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Please replace paragraph [0030] in the specification, page 6, line 21 – page 7, line 3 with the following amended paragraph:

[0030] The inner protective sheath 12 provides additional wear resistance. Generally, the inner protective sheath 12 may function to support the general shape and configuration of the first portion 8. Preferably, the inner protective sheath 12 is flexible yet resistant to wear. In some preferred embodiments of the present invention, the inner protective sheath 12 may be constructed of silicone rubber or a similar polymer known as **Nusil.TM.** **NUSIL® silicone amine**. Silicone and **Nusil.TM.** **NUSIL® silicone amine** also have the advantage that they are relatively transparent and enable easy inspection as to the condition and quality of the inner protective sheath 12.

Please replace paragraph [0032] in the specification, page 7, lines 14-22 with the following amended paragraph:

[0032] Within the electromagnetic shielding layer 13 may be a wire bundle 14 which contains the wires to act as an electrical conduit for the lead assembly. The wire bundle is generally assembled by inter weaving several insulated wires 15 with each other and a wiring strain relief 17. The position of the wires and the mechanical strain relief set in place using second layer of silicone or **Nusil.TM.** **NUSIL® silicone amine**. Preferably, the lead assembly 10 includes three wires, but any number of wires are possible. An increase in the number of wires will increase the overall minimum diameter of the lead assembly, therefore it is preferred to include a minimum amount of insulated wires to provide functionality to the implantable medical device for which the lead assembly is to cooperate.

Please replace paragraph [0033] in the specification, page 7, line 23 – page 8, line 2 with the following amended paragraph:

[0033] Preferably, the wiring strain relief 17 is constructed from 2 **Kevlar.TM.** **KEVLAR® fiber** cords with a combined approximate breaking strain of 630N. Additionally, the wires 16 within the wire bundle 14 should

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be separately insulated preferably using Perfluoroalkoxy ('PFA') insulation
15.

Please replace paragraphs [0035 - 0037] in the specification, page 8, lines 6-23
with the following amended paragraphs:

[0035] Preferably, at least a segment of second portion 4 is covered with a textured outer surface 19. The textured outer surface 19 may be constructed of velour or ~~Dacron.TM.~~ DACRON® polyester. This textured surface may permit a patient's body to ingrow into regions of the lead assembly covered with this textured surface 19. It may also be noted that the textured surface preferably only coats regions of the lead assembly which necessarily must be anchored to the patient's body. Portions of the relatively ~~thin region 20~~ thin region 6 which extend externally from the patient's body may not require a textured surface for this reason.

[0036] The outer protective layer 21, in this embodiment, performs a similar function of the inner protective sheath 12 described in relation to FIG. 2. The outer protective layer 21 adds further wear resistance, may be flexible, may be substantially biocompatible and may be suitable for implantation. The outer protective layer 21 may be constructed of silicone or ~~Nusil.TM.~~ NUSIL® silicone amine.

[0037] Beneath the outer protective layer 21 preferably is a wire bundle 22. This wire bundle 22 may include: three wires 25 (which are insulated preferably by PFA 23), a wiring strain relief 24, and some silicone or ~~Nusil.TM.~~ NUSIL® silicone amine to provide dimensional support. The wire bundle 22 may be constructed in similar manner to the wire bundle 14 depicted in FIG. 2.

Please replace paragraph [0041] in the specification, page 9, lines 17-19 with the following amended paragraph:

[0041] Additionally, the size of the hole 5 is ~~minimised~~ minimized because of the thickness of the relatively thin region 6. This ~~minimisation~~

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minimization reduces the probability of infection and promotes wound healing by the patient's body.

Please replace paragraphs [0048 - 0050] in the specification, page 8, line 11 – page 12, line 2 with the following amended paragraphs:

[0048] The embodiment is shown in FIG. 6, depicts a preferred lead restraint 35 is depicted. This preferred lead restraint 35 includes: a flexible strip 40, interlocking ~~Velcro.TM.~~ fastener segments 43 & 44 and adhesive 41.

[0049] Preferably, the lead restraint 35 is constructed by gluing a portion of the flexible strip 40 to the surface skin layer 26 of a patient. This may be accomplished by applying adhesive 41 to the locations depicted in FIG. 6. Attached to the opposed surface of flexible strip 40, which was glued to the patient's skin, may be attached at least two segments of interlocking and complementary ~~Velcro.TM.~~ fastener regions 43 & 44 ~~regions~~. This arrangement preferably allows the flexible strip 40 to fold and allow the complementary fastener regions ~~Velcro.TM.~~ 43 & 44 ~~regions~~ to interlock and/or connect.

[0050] Preferably, the relatively thin region 6 of the lead assembly 10 is positioned between the two interlocking fastener layers ~~of Velcro.TM.~~ 43 & 44. The relatively thin region 6 may be secured in place by the lead restraint 35. Preferably, the interlocking regions 43 & 44 secure the relatively thin region 6 firmly enough so as to restrain the lead from accidental stress induced by pulling or stretching. Please note that the lead restraint 35 may be positioned to also restrain the first portion 8.